K053413

510(k) SUMMARY as required by 807.92 APR 6 2006
Summary of Safety & Effectiveness Information

1. Device Name

Proprietary Name

Terumo® Syringe for administration of UV sensitive medicines

Classification Name

Piston syringe (80FMF)

21CFR, Section 880.5860

Classification: Class II

Common Name

Sterile hypodermic syringe for single use

2. Reason for Submission

New Device

3. Intended Use

The Terumo Syringe for administration of UV sensitive medicines is a sterile hypodermic syringe for single use, intended for the aspiration of fluids and blood, or for the injection of fluids immediately after filling. The opaque color of the barrel allows the administration of UV sensitive medicines.

4. Description & Materials

The Terumo Syringe for administration of UV sensitive medicines is a hypodermic standard piston syringe, available in 20 ml volume, with an eccentric luer taper tip for single use, made of plastic material and a synthetic rubber gasket. The barrel of the syringe has an opaque color to avoid the transmission of UV light.

5. Technology/Principles of operation

The Terumo Syringe is operated manually.

6. Performance

The Terumo syringe was tested in accordance with EN ISO 7886-1 (1997). Other testing included barrel transmission and UV protection of the opaque barrel.

None of the data raises any new issues of safety and effectiveness.

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7. Substantial Equivalence

The "Terumo Syringe for administration of UV sensitive medicines", manufactured by Terumo Europe N.V., submitted in this 510(k) file is substantially equivalent in intended use, description/specifications, technology/principles of operation, materials and performance to the cleared "Terumo Disposable Hypodermic Syringe", manufactured by Terumo Medical Corporation in which is the subject of K980181, with the exception that the opaque colored Terumo Syringe manufactured by Terumo Europe N.V. additionally allows the administration of UV sensitive medicines.

8. Additional Safety Information

The sterility of the Terumo Syringe for administration of UV sensitive medicines is assured by using a validated sterilization method qualified in accordance with EN 550: "Sterilization of Medical Devices: Validation and routine control of ethylene oxide" and ISO 11135: "Medical Devices: Validation and routine control of ethylene oxide sterilization" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels and Ethylene Chlorohydrin residual levels resulting from EtO sterilization are in compliance with ISO 10993-7: " Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals".

The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard EN ISO-10993, "Biological Evaluation of Medical Devices
Part-1: Evaluation and testing. Results of the testing demonstrate that the blood contacting materials are biocompatible.

The expiration dating for the Terumo Syringe for administration of UV sensitive medicines has been established at 5 years.

9. Conclusion

The Terumo Syringe for administration of UV sensitive medicines manufactured by Terumo Europe N.V. and submitted in this 510(k) file is substantially equivalent in intended use, description, specifications, technology/principles of operation, materials and performance to the cleared Terumo Disposable Hypodermic Syringe manufactured by Terumo Medical Corporation which is the subject of K980181, with the exception that the opaque colored Terumo Syringe manufactured by Terumo Europe N.V. additionally allows the administration of UV sensitive medicines.
Differences between the devices do not raise any new or different issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

Ms. M.J. Aerts
Manager Regulatory Affairs
TERUMO EUROPE N.V.
Researchpark Zone 2
Interleuvenlaan 40
Leuven, Belgium 3001

Re: K053413
Trade/Device Name: Terumo® Syringe for Administration of UV Sensitive Medicines
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: February 20, 2006
Received: February 23, 2006

Dear Ms. Aerts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

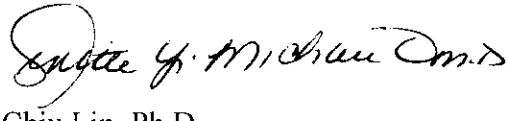
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053413

Device Name: Terumo® Syringe for administration of UV sensitive medicines

Indications for Use:

The Terumo Syringe for administration of UV sensitive medicines is a sterile hypodermic syringe for single use, intended for the aspiration of fluids and blood, or for the injection of fluids immediately after filling. The opaque color of the barrel allows the administration of UV sensitive medicines.

Prescription Use X S.N 4/5/06 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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...ny, General Hosp...

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